MaineCare Services
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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TO: Maine Drug Utilization Review Board
DATE: September 14, 2015
RE: Maine DUR Board **Meeting** minutes from September 8, 2015

ATTENDANCE	**PRESENT**	**ABSENT**	**EXCUSED**
Linda Glass, M.D.			X
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mark Braun, M.D., FACP, Internist/Geriatrician			X
Mike Ouellette, R.Ph., GHS	X		
Jeffrey S. Barkin MD, DFAPA	X		
Non –Voting			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Roger Bondeson, Director of Operations, OMS	X		

Guests of the Board: Jacquelyn Hedlund, MD and Mike Antoniello, MD

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Paul Skodny, from Amgen presented Repatha®. Repatha® is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated as an adjunct to diet and:

- Maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholeste rolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).
- Other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

The effect of Repatha® on cardiovascular morbidity and mortality has not been determined. Safety and efficacy of Repatha® was studied in 4 double-blind, randomized, placebo-controlled trials. Primary end point for all studies was percent change in LDL from baseline. Common adverse reactions in clinical trials (> 5% of patients treated with Repatha® and occurring more frequently than placebo): nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

Bob Pitasi, from Otsuka presented Rexulti®. Rexulti® is an atypical antipsychotic indicated for:

- Use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD)
- Treatment of schizophrenia

Safety and efficacy of Rexulti® for major depressive disorder and schizophrenia were each studied in a 6 week, placebo-controlled, fixed-dose clinical trials in patients with MDD and patients with schizophrenia. Most common adverse reactions for MDD were weight increased and akathisia (≥5% and at least twice the rate for placebo), for Schizophrenia weight increased (≥4% and at least twice the rate for placebo). Rexulti's box warning an increased mortality in elderly patients with dementia- related psychosis; and suicidal thought and behaviors. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death. REXULTI is not approved for the treatment of patients with dementia-related psychosis. Antidepressants increase the risk of suicidal thoughts and behaviors in patients aged 24 years and younger. Monitor for clinical worsening and emergence of suicidal thoughts and behaviors. Safety and effectiveness of Rexulti® have not been established in pediatric patients.

Mary Ellen Corrigan, Nurse Practitioner for the Cystic Fibrosis Center in Portland, Maine. Spoke on behave of Orkambi®.

Shaffee Bacchus, from Janssen presented Invega Trinza®. Invega Trinza®, a 3-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with Invega sustenna® (1-month paliperidone palmitate extended-release injectable suspension) for at least four months. The most common adverse reactions (incidence ≥ 5% and occurring at least twice as often as placebo) were injection site reaction, weight increased, headache, upper respiratory tract infection, akathisia, and parkinsonism.

Thomas Algozzine, from Novartis presented Entresto®. Entresto® is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker, indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II -IV) and reduced ejection fraction. In the double-blind period, safety was evaluated in 4, 203 patients treated with Entresto® and 4, 229 treated with enalapril .In PARADIGM-HF, patients randomized to Entresto® received treatment for up to 4.3 years, with a median duration of exposure of 24months; 3,271patients were treated for more than one year. Discontinuation of therapy because of an adverse event during the double-blind period occurred in 450 (10.7%) of Entresto® treated patients and 516 (12.2%) of patients receiving enalapril. Adverse reactions occurring ≥5% are hypotension, hyperkalemia, cough, dizziness, and renal failure. The recommended starting dose of Entresto® is 49/51mg (sacubitril/valsartan) twice-daily. Double the dose of Entresto® after2 to 4 weeks to the target maintenance dose of 97/103 mg (sacubitril/valsartan) twice-daily, as tolerated by the patient.

Bruce Sill, from BMS presented Daklinza®. Daklinza® is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infection. The recommended dosage of Daklinza® is 60 mg, taken orally, once daily in combination with sofosbuvir for 12 weeks. Daklinza® may be taken with or without food. FDA approval was based off of the ALLY-3 trial, 152 treatment-naive and treatment-experienced subjects with HCV genotype 3 infection were treated with Daklinza® 60 mg once daily in combination with sofosbuvir for 12 weeks. Most common adverse reactions (≥10%) observed with Daklinza® in combination with sofosbuvir were headache and fatigue.

OLD BUSINESS

DUR MINUTES

The June 2015 minutes were approved.

PSYCH WORK GROUP UPDATE

No update at this time

MAINECARE UPDATE

Roger Bondeson stated that the DUR board members will be going from a contract to a Memorandum of Understanding (MOU). Along with the MOU, a finical discloser and business associate agreement will be sent out to the current board members from the State of Maine contract department.

NEW BUSINESS

BEHAVIOR HEALTH MEDICATIONS

Mike Ouellette, from Goold Health Systems presented data to the board on behavior health medications of MaineCare members under the age of 21. This report is informational for the board and is sent the State of Maine quarterly.

Board Decision: No action required

SUBOXONE AND OPIATE REPORTS

Mike Ouellette, from Goold Health Systems presented data to the board on Suboxone and Opiate reports. These reports are also sent to the state of Maine. In the Suboxone report you can see the decrease in the number of restarts this relates to the 2year limit that the state put into place. Also included is the monthly trend roughly around 2500 patients. The average dose is relatively flat at 11.5mg. In the opiate report it shows the change in number of patients taking opiate <=15days, 15-29days, 30-43days, 44-57days and >57days. The second report is tracking the morphine sulfate equivalency (MSE) level.

Board Decision: No action required

PCSK9 INHIBITORS

Dr. Jeffery Barkin, from Goold Health Systems presented an informational document on PSCK 9 Inhibitors. Also included is an editorial from the New England Journal of medicine called Lowing LDL Cholesterol Is Good, but How and in Whom? This will be looked into further at a later meeting.

Board Decision: No action required

SSDC UPDATES/ANNUAL MEETING

Mike Ouellette, from Goold Health Systems gave a brief SSDC update. October 13, 2015 will be the annual PDL review from 1pm -5pm.

Board Decision: No action required

NEW DRUG REVIEW

Aptensio XR the common name is methylphenidate extended-release in the PDL category stimulant methylphenidate, long-acting. Aptensio® XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (AHDH).

Recommendation: The recommendation is for Aptensio® XR it to be non-preferred.

Asmanex HFA the common name is mometasone in the PDL category antiasthmatic- steroid inhalants. For maintenance treatment of asthma as prophylactic therapy in patients who are ≥12 years of age. Asmanex® HFA is NOT indicated for the relief of acute bronchospasm.

Recommendation: It is recommended that Asmanex HFA® remain non-preferred and require clinical prior authorization to verify diagnosis and appropriate lab testings.

Daklinza the common name is daclatasvir dihydrochloride in the PDL category hepatitis c agents. For use with sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV) genotype 3 infections. Sustained virologic response (SVR) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving Daklinza® in combination with sofosbuvir for 12 weeks.

Recommendation: The recommendation is for Daklinza® to be non-preferred.

Entresto the common name is sacubitril/valsartan in the PDL category ARB combinations. To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto® is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

Recommendation: The recommendation is for Entresto® to be non-preferred.

Glatopa the common name is glatiramer acetate in the PDL category multiple sclerosis- non interferons. Indication is for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Recommendation: The recommendation is for Glatopa® to be non-preferred.

Invega Trinz Inj the common name is paliperidone palmitate injection, extended-release in the PDL category antipsychotics, atypical. Indication is a 3-month injection for the treatment of schizophrenia in patients after they have been adequately treated with Invega® Sustenna (1-month paliperidone palmitate extended-release injectable suspension) for at least 4 months.

Recommendation: The recommendation is for it to be non-preferred.

Irenka the common name is duloxetine, delayed release in the PDL category antidepressnats-selected SSRIs. For the treatment of: major depressive disorder (MDD), generalized anxiety disorder (GAD), diabetic peripheral neuropathy, and chronic musculoskeletal pain.

Recommendation: The recommendation is for Irenka® to be non-preferred.

Orkambi the common name is lumacaftor/ivacaftor in the PDL category cystic fibrosis agents. For the treatment of cystic fibrosis (CF) in patients 12 years of age and older who are homozygous for the *F508del* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene

Recommendation: The recommendation is for Orkambi® to be non-preferred.

Prestalia the common name is perindopril arginine/ amlodipine in the PDL category ACE-Inhibitors & Ca channel blockers. For the treatment of hypertension, to lower blood pressure (BP). It may be used in patients whose BP is not adequately controlled on monotherapy OR it may be used as initial therapy in patients likely to need multiple drugs to achieve BP goals. The use of Prestalia® is not recommended in patients with heart failure.

Recommendation: The recommendation is for Prestalia® to be non-preferred.

Rexulti the common name is brexpiprazole in the PDL category antipsychotics-atypical. For adjunctive treatment of major depressive disorder (MDD) AND treatment of schizophrenia. Rexulti® is not approved for the treatment of patients with dementia-related psychosis.

Recommendation: The recommendation is for Rexulti® to be non-preferred.

Stiolto Respimat the common name is tiotropium bromide & olodaterol in the PDL category antiasthmatic- adrenergic anticholinergic. The indication is for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Stiolto® Respimat is NOT indicated to treat acute deteriorations of COPD and is NOT indicated to treat asthma.

Recommendation: The recommendation is for Stiolto® Respimat it to be non-preferred.

Technivie the common name is ombitasvir/paritaprevir/ritonavir in the PDL category hepatitis c agents. The indication is for in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis. Technivie® is not recommended for use in patients with moderate hepatic impairment.

Recommendation: The recommendation for Technivie® to be non-preferred.

FDA SAFETY ALERTS

Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm454141.htm

Unapproved Prescription Ear Drop (Otic) Products: Not FDA Evaluated for Safety, Effectiveness and Quality
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453430.htm

Codeine Cough-and-Cold Medicines in Children: Drug Safety Communication - FDA Evaluating Potential Risk of Serious Side Effects
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm

FDA Issues the Drug Supply Chain Security Act (DSCSA) Implementation: Product Tracing Requirements for Dispensers–Compliance Policy Guidance
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

FDA Drug Safety Communication: FDA reporting permanent skin color changes associated with use of Daytrana patch (methylphenidate transdermal system) for treating ADHD
http://www.fda.gov/Drugs/DrugSafety/ucm452244.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Brintellix (vortioxetine) and Brilinta (ticagrelor): Drug Safety Communication - Name Confusion
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm

Picato (ingenol mebutate) Gel: Drug Safety Communication - FDA Warns of Severe Adverse Events, Requires Label Changes
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm459311.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Board Decision: No action required

ADJOURNMENT: 8PM

The next meeting will be held on **October 13, 2015** 1:00p.m. – 4:00p.m at the Augusta Armory.